

Comments

**On Draft Guidelines for Ensuring and Maximizing
The Quality, Objectivity, Utility and Integrity Of
Information Disseminated by the Environmental
Protection Agency (Docket Number OEI-10014)**

By the National Association of Manufacturers

Submitted to the Environmental Protection Agency on
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Executive Summary

On April 30, 2002, the Environmental Protection Agency (EPA) released for public comment its Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the EPA. The EPA requests comments and input on several issues, including what classes of information constitute “influential” information; how to address information generated by third parties; and feedback on the EPA’s complaint-resolution process.

The information disseminated by the EPA is a critical management tool for manufacturers to address environmental problems, develop solutions, set priorities and maintain compliance with environmental statutes and regulations. Therefore, the National Association of Manufacturers (NAM) welcomes the opportunity to help the EPA develop guidelines that will ensure the quality of the EPA’s data. The NAM believes that the key to maintaining economic growth while improving our environment lies, first and foremost, in basing environmental priorities on sound science. Accordingly, the NAM believes that information-quality guidelines should address concerns about the accuracy of disseminated data, the timeliness of information, the scope of available data and the adequacy of placing accurate data in context with regulatory decision-making.

While the Draft Guidelines provide a strong foundation for improvement in the overall quality of information that the EPA disseminates to the public, the NAM has six key concerns with the guidelines:

- the Draft Guidelines exclude too much information from coverage and create significant exemptions to the guidelines’ applicability;
- the Draft Guidelines do not ensure transparency that facilitates the reproducibility of certain types of information;
- the Draft Guidelines fail to develop a process for pre-dissemination review;
- the Draft Guidelines adopt an inadequate complaint-resolution process;
- the Draft Guidelines are unclear regarding retroactivity of information-quality standards for disseminated information; and
- the EPA inappropriately attempts to restrict the application and enforceability of the Draft Guidelines.

The NAM will address each of these concerns in its comments and make recommendations to alleviate the concerns.

Once again, the NAM appreciates the EPA’s request for public assistance in the formulation of the information-quality guidelines. It is important that these guidelines be drafted to ensure they are workable, effective and provide the regulated community with the confidence in the EPA’s information products, communication activities and regulations.

COMMENTS OF THE
NATIONAL ASSOCIATION OF MANUFACTURERS
To the
ENVIRONMENTAL PROTECTION AGENCY

Regarding
DOCKET NUMBER OEI-10014

On
DRAFT GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY,
OBJECTIVITY, UTILITY AND INTEGRITY OF INFORMATION DISSEMINATED BY
THE ENVIRONMENTAL PROTECTION AGENCY

Introduction

The National Association of Manufacturers (NAM) submits these comments in response to the Environmental Protection Agency (EPA) Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency (hereinafter, Draft Guidelines), as published in the April 30, 2002, *Federal Register*. The NAM is the nation's largest industrial trade association. The NAM represents 14,000 member companies (including 10,000 small and mid-sized companies) and 350 member associations serving manufacturers and employees in every industrial sector and all 50 states.

For NAM member companies, associations and state affiliates, information disseminated by the EPA is a critical management tool used to frame environmental problems and solutions, set priorities and maintain compliance with environmental requirements under various environmental statutes and regulations. The NAM believes that the key to maintaining economic growth while improving our environment lies, first and foremost, in basing environmental priorities on sound science. Accordingly, the NAM has a vested interest in the EPA's development of information-quality guidelines that will affect a broad array of industry owners and operators, particularly small businesses of various kinds. Our comments will address those general issues of concern presented in the Draft Guidelines.

Key Concerns and Recommendations

The Draft Guidelines exclude too much information from coverage and create significant exemptions to the guidelines' applicability. The EPA's final guidelines should conform to the Data Quality Act and the Office of Management and Budget implementing guidelines by ensuring broad applicability and eliminating exclusions of large categories of information from coverage.

The Draft Guidelines do not ensure transparency that facilitates the reproducibility of certain types of information. In particular, the EPA's final guidelines should require that all influential scientific information be reproducible, especially when various models developed by third parties are used to formulate policies based upon influential scientific information.

The Draft Guidelines fail to develop a process for pre-dissemination review. The EPA's final guidelines should develop a process for reviewing the quality of information before it is disseminated.

The Draft Guidelines adopt an inadequate complaint-resolution process. The EPA's final guidelines should correct flaws in the complaint-resolution process regarding time frames for decisions, objectivity concerns, appeals and requests for corrections.

The Draft Guidelines are unclear regarding retroactivity of information-quality standards for disseminated information. The EPA's final guidelines should make it clear that any information disseminated prior to October 1, 2002, and thus not subject to the guidelines, will become subject to the guidelines if it is redisseminated after October 1, 2002.

The EPA inappropriately attempts to restrict the application and enforceability of the Draft Guidelines. The EPA's final guidelines should accept that its requirements are legally binding on the agency.

Background

The Need for Information-Quality Guidelines

In the pursuit of environmental and economic growth objectives, manufacturers look to the EPA as an essential source of information. Therefore, the EPA's approach to the collection, use and dissemination of environmental information is vital to the business sector. To this end, the EPA needs to ensure that the information it disseminates is accurate, objective and useful.

Information quality is integral to the EPA's mission, as the agency's decisions based on that information influences all sectors of the manufacturing community. The NAM commends the EPA for engaging the public in the formulation of its information-quality guidelines.

A consistent set of information-quality guidelines across the full range of environmental information sources is crucial to this effort. Environmental information originates from a broad spectrum of sources, including state and local governments, federal agencies, public interest groups and the private sector. Because of the individual objectives and missions of this heterogeneous collection of entities, information-quality guidelines require affected party involvement, protection of fundamental interests (*e.g.*, confidentiality, national security) and reasonable recourse for adverse dissemination and policy decisions. The EPA has a real opportunity to advance a strong commitment to data quality through its final guidelines while protecting the interests of those it wishes to serve.

The EPA exercises tremendous power over companies, facilities and products through its information use and dissemination. As mentioned above, some of this information is derived from business data for public purposes. In other cases, the private sector uses data and other forms of information drawn from other sources to maintain compliance with environmental regulations and develop energy efficient and environmentally sound processes and products. In either case, the EPA must design and maintain its information systems to ensure and maximize the quality, objectivity, utility and integrity of information it disseminates.

OMB Guidelines

In Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Congress directed the Office of Management and Budget (OMB) to issue government-wide guidelines that “provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information disseminated by federal agencies.” The OMB guidelines direct agencies subject to the Paperwork Reduction Act (PRA) to:

- issue their own information-quality guidelines to ensure and maximize the quality, objectivity, utility and integrity of information by Oct. 1, 2002;
- establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by an agency that does not comply with OMB guidelines; and
- report to the director of OMB the number and nature of complaints received by the agency regarding agency compliance with OMB guidelines and how such complaints were resolved.

The OMB guidelines provide a strong foundation for improvement in the overall quality of information that the federal government disseminates to the public. They also provide some basic principles for agencies to adopt when developing their own guidelines. According to the OMB, guidelines should be flexible enough to address all communications media and the importance of information products; some agency information may need to meet higher expectations; and agencies should adopt a common-sense approach that builds on existing processes and procedures. Accordingly, the EPA should draft its guidelines in such a way as to ensure they are workable, effective and in keeping with the government-wide standards set by the OMB. In addition, on June 10, 2002, the administrator of the Office of Information and Regulatory Analysis (OIRA) issued a memorandum to the President’s Management Council (hereinafter, June 10 OIRA Memo) giving the various agencies additional guidance based on a review of the agencies’ draft guidelines.

EPA Guidelines

The EPA has numerous systems and practices currently in place that are designed to address the quality, objectivity, utility and integrity of information. For example, the EPA Agency-Wide Quality System helps ensure that EPA organizations maximize the quality, objectivity, utility and transparency of information disseminated by the agency. Second, the EPA’s Peer Review Policy provides that major scientifically and technically based work products related to agency decisions normally should be peer-reviewed. A third example is the agency’s Action Development Process that also serves to ensure and maximize the quality of disseminated information. Finally, the EPA’s Integrated Error Correction Process reports and resolves data errors identified by the public in the EPA’s information holdings. Analysis of existing information-quality processes is beyond the scope of these comments, but it is important to stress that the final guidelines must coordinate, improve and build upon the information-quality systems already in place at the EPA.

The OMB guidelines call for agencies to define “influential” information so that the agencies can reasonably determine that dissemination of the information will have a clear and substantial impact on important public policies or important private-sector decisions. The EPA adopts the OMB language and then specifies several types of information that will be generally considered “influential,” such as those that appear to meet the definition of a significant regulatory action, and major scientific and technical work products undergoing peer review. The OMB also calls for information that is capable of being substantially reproduced. If access to data and methods will not occur, due to compelling interests such as privacy, trade secrets, national security or other reasons, OMB guidelines require robustness checks so that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision.

The OMB guidelines state that science-quality and risk-assessment standards contained in the 1996 amendments to the Safe Drinking Water Act (SDWA) should be adopted or adapted by federal agencies. The OMB states only two valid reasons why a federal agency should not adopt the standards: the agency does not conduct health-risk assessments; or the SDWA risk-assessment standards conflict with the specific risk-assessment standards of another federal statute governing the agency. The EPA Draft Guidelines adopt the SDWA science-quality standards, but state that the EPA will only adapt the SDWA risk-assessment standards, without explaining how or why. Thus, the EPA is required to either “adopt the SDWA language or explain how the SDWA language conflicts with one or more relevant statutes and provide specific adaptive language for those specific instances where a conflict exists.”

The EPA recognizes in the Draft Guidelines that third-party information is complex and requires more collaboration with states, scientists and other external data providers. The EPA states that it needs to take steps to ensure that the quality and transparency of data and information provided by third parties is sufficient for the intended use.

The EPA developed a complaint-resolution process by which an initial complaint would be heard by the EPA person with the responsibility for the quality of the information disseminated by the EPA. Any appeals would be heard by the assistant administrator (AA) or regional administrator (RA) for that program or region. The appeal would be decided in collaboration with a standing panel consisting of other AAs and RAs, chaired by the EPA chief information officer.

Discussion

The Draft Guidelines exclude too much information from coverage and create significant exemptions to the guidelines’ applicability.

The Draft Guidelines propose exemptions to the Data Quality Act not authorized by Congress or the OMB. According to the Draft Guidelines, materials that constitute “information” that the EPA “disseminates” to the public would be covered by the guidelines. The EPA offers four situations that constitute “dissemination” of “information”:

- The EPA prepares the information and distributes it to support or represent the EPA’s viewpoint, to formulate/support a regulation, guidance or other agency position.
- The EPA distributes information prepared by an outside party in a manner that reasonably suggests that the EPA endorses or agrees with it, if the EPA indicates its

support for the information or if the EPA proposes to use the information to formulate or support a regulation, guidance, policy or other agency position.

- The EPA reviews and comments on information distributed by an outside party or adopts or endorses it.
- Distributions by outside parties are not considered to be “sponsored” by the EPA unless the agency is using the outside party to disseminate information on the agency’s behalf.

The Draft Guidelines, however, then go on to list three pages of what is “not covered” by the Draft Guidelines, including the following:

- distribution limited to government employees;
- intra- or inter-agency use or sharing of government information;
- EPA responses to requests for agency records;
- distribution of information in correspondence with individuals or persons;
- distribution of information in press releases and similar announcements;
- distribution of background and outdated or superseded information;
- distribution of information by federal employees and recipients of grants, cooperative agreements and contracts;
- distribution of information in public filings, including filings required by statutes, regulations, orders, permits or licenses and information submitted voluntarily to the EPA;
- distribution related to subpoenas or adjudicative processes; and
- the EPA may identify other instances where information is not “disseminated” by the EPA because the EPA does not initiate or sponsor the distribution of information.

The OMB guidelines expressly exempted certain obvious distributions, such as inter-agency distributions and distributions limited to employees. However, the EPA’s Draft Guidelines, through multiple exemptions, is attempting to further limit the definition of “dissemination.” The EPA has crafted significant exemptions to the OMB-guidelines’ applicability, excluding large categories of information from coverage with its expansive interpretations of the scope of information in public filings, subpoenas and adjudicative processes. The following exemptions are of particular concern to the NAM:

1. The OMB guidelines exclude “adjudicative processes” from coverage and do not define the term. If this exclusion is defined overly broadly, this could remove large quantities of information from the information-quality standards. The exclusion should be limited to actual, not contemplated or potential, judicial proceedings and to certain administrative proceedings. Moreover, the exclusion should be limited to documents and other agency information prepared specifically and only for actual judicial proceedings or certain administrative adjudications. In addition, scientific, financial or statistical information used in court settlements in which the EPA is a party must not be excluded from the guidelines’ coverage. Court settlements can have the same legal effect as regulations; therefore, the data used should meet the same standards. The EPA Draft Guidelines’ “adjudicative processes” exclusion is

grossly overbroad and encompasses many agency proceedings (*e.g.*, processing of applications for permits, licenses, registration, waiver, exemption or claim) that are not adjudicatory under any common use of the term.

2. The EPA has reserved to itself the right to “identify other instances where information is not disseminated by the EPA because the EPA does not initiate or sponsor the distribution of information.” This statement, standing alone, implies excessive discretion to exempt “third-party” information. However, in his June 10, 2002 OIRA Memo to agencies, Dr. John Graham praises the EPA with respect to coverage of “third-party” information for explicitly stating that “the guidelines may still apply to a subsequent distribution of the information in which EPA adopts, endorses or uses the information to formulate or support a regulation, guidance, or other agency decision or position.” The NAM would appreciate it if the agency would ensure the proper qualifications, including the June 10 directions from OIRA, are integrated in its final guidelines.
3. For scientific, financial or statistical information deemed “influential,” the OMB mandates that agency guidelines include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties. The EPA adopts the OMB’s definition of “influential” – the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private-sector decisions.” The Draft Guidelines, however, consider only information used to support “top” agency actions to be “influential” information. Information used to support any EPA rulemaking, guidance, decision or position should be within the definition of influential information and subject to the final guidelines.
4. The EPA is apparently trying to limit the use of “influential” scientific, financial or statistical information to that which is “disseminated in support of OMB Economically Significant actions.” This limitation would exempt scientific, financial or statistical information that is admittedly influential from all non-major rulemakings and to all EPA-sponsored or approved scientific studies. The EPA has many rulemakings that are very important to manufacturing sectors that do not meet the “Economically Significant” threshold. Similarly, past studies endorsed by the EPA have had large effects on the public and Congress. There is simply no compelling reason why small business sectors – any more than large business sectors – should be subject to rules based on bad science.

In sum, the EPA’s final guidelines should conform to the Data Quality Act amendments to the Paperwork Reduction Act, the OMB’s implementing guidelines and the June 10 OIRA memorandum by ensuring broad applicability and eliminating exclusions of large categories of information from coverage that are not authorized by the information dissemination requirements of the PRA.

The Draft Guidelines do not ensure transparency that facilitates the reproducibility of certain types of information.

The EPA often uses various models and other information created by third parties to formulate policies based upon influential scientific information. The EPA also frequently uses a third party's analysis of underlying data. The third-party models are sometimes asserted to be confidential and proprietary. The OMB guidelines require that influential scientific information be reproducible. The EPA Draft Guidelines recognize that influential scientific, financial or statistical information should be subject to a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties. According to the Draft Guidelines, if access to data and methods cannot occur due to privacy, trade secrets and other confidentiality protections, the EPA should apply robustness checks to analytic results and document what checks were taken.

The EPA's final guidelines should require that all influential scientific information be reproducible, especially when various models developed by third parties are used to formulate policies based upon influential scientific information. Public disclosure of third-party models should be required in all but the most unusual circumstances. In such circumstances, the EPA should apply rigorous robustness checks and disclose the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed. The EPA should use proprietary third-party data only as a last resort when non-confidential information cannot be used. The use of proprietary models has become disruptive to public access to scientific information that has been used as the basis to formulate major policies.

For example, the EPA has for years been using a proprietary econometric model developed by ICF Consulting whenever the EPA needs to justify its decisions regarding emissions reductions from power plants. This model is not available for public review because it is "proprietary." The EPA is currently basing its Clear Skies Initiative reduction levels for sulfur dioxide, nitrogen oxides and mercury on the results of the ICF model. The EPA claims the reduction levels it is proposing will not result in higher electricity prices nor result in fuel switching from coal to natural gas. Industry has made multiple efforts to have the EPA explain the results of the ICF multi-emissions analysis, but to no avail.

The Department of Energy uses the publicly available Energy Information Administration (EIA) model to produce its own results, which differ substantially from the EPA's numbers. The DOE has been precluded from examining the ICF model due to its proprietary status. The electric utility industry has been using another publicly available model and has also produced substantially different results than the ICF results. Serious legal and public notice problems exist in making substantial public-policy decisions based on a proprietary model that not only cannot be reviewed by the public, but that also differs significantly in its results from an established public model and a respected private model.

The Draft Guidelines fail to develop a process for pre-dissemination review.

The OMB guidelines direct agencies to develop a process for reviewing the quality of information before it is disseminated. The EPA's response in its Draft Guidelines is to state that it will incorporate the information-quality principles into existing pre-dissemination review

procedures as appropriate. This does not adequately address the issue of pre-dissemination review. This is an OMB priority and the EPA needs to focus more on it in its final guidelines. The EPA's final guidelines should develop a process for reviewing the quality of information before it is disseminated. The EPA's pre-dissemination review process should specify steps that will enable the agency to exercise full stewardship of information, from validity of primary data to quality controls on information products.

The NAM also recommends that the EPA consider adopting the OMB guidelines for internal procedures in the development of information products, including: pursuing the most knowledgeable and reliable sources reasonably available to confirm the objectivity and utility of information; consulting with all OMB divisions with substantial interest and expertise and, where appropriate, other federal offices, non-governmental organizations and the public; and considering the uses of the information.

The Draft Guidelines adopt an inadequate complaint-resolution process.

The OMB guidelines direct agencies to "establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines." Affected persons must also be given a right to appeal any denial of their correction request.

The definition of "affected person" is important, as it determines who is and is not eligible to file an administrative petition for a correction of agency-disseminated information. The Draft Guidelines define "affected persons" as persons who may benefit or be harmed by the disseminated information. However, this definition is too limited. The EPA should adopt the Health and Human Services (HHS) open approach to the "affected persons" definition wherein the HHS policy is to ask the complainant to "describe how the person submitting the complaint is affected by the information error."

The OMB guidelines require agencies to specify appropriate time periods for decision-making on a complaint. However, the EPA's Draft Guidelines ignore this issue and do not specify any time period for decisions on information corrections. The EPA must establish a reasonable time period within which it will respond to requests for correction of information. The time limit for EPA review of complaints should be reasonably short (30-45 days for each stage), although flexible for complex issues.

The EPA Draft Guidelines outline a process by which the Office of Environmental Information (OEI) will receive complaints and distribute them to the appropriate EPA "information owner." Information owners are the responsible persons designated by the EPA in the applicable program office or who have responsibility for the quality, objectivity, utility and integrity of the information product or data disseminated by the EPA. As currently proposed, both the initial decision and the appeals decision would be made within the organization that generated the information originally. The EPA should incorporate more objective review and decisions into its information-correction process. It may be appropriate to assign the OEI a greater role in the review and decision process, or to create a separate objective entity, independent of the program offices, to be involved in review and decisions, especially for appeals. Either way, the EPA final

guidelines should recognize the need for a balance between the reviewers' knowledge of the subject matter and the reviewers' objectivity.

According to the Draft Guidelines, the EPA may elect not to correct some completed information products on a case-by-case basis, due to agency priorities, time constraints or resources. Congress and the OMB require the EPA to establish mechanisms that allow persons to seek and obtain timely correction of information. The EPA must do more than simply respond to a request for correction; it must actually make the correction. Agency priorities, time constraints or resources must not be a factor; whether information is corrected should be based on the validity of the request. The final guidelines must clarify that when the EPA approves a request for correction of information, that information will be corrected.

The NAM objects to the EPA's exclusion from the information-correction process information that "...pertains to EPA actions, where a mechanism by which to submit comments to the agency is already provided. For example, EPA rulemakings include a comprehensive public comment process and imposes a legal obligation on the EPA to respond to comments on all aspects of the action." Even data used for a rulemaking should be subject to data-quality complaints outside the rulemaking process. The effect of the EPA exclusion would be to essentially defend poor data used in rulemakings, unless specific mention is made during the short rulemaking public comment period. The exclusion would undermine, in practice, the goals of the Data Quality Act.

The Draft Guidelines are unclear regarding retroactivity of information-quality standards for disseminated information.

The EPA is to be commended for making it clear that information not previously covered by the guidelines may be subject to the guidelines upon a subsequent distribution if the subsequent distribution meets the definition of dissemination. However, the EPA should make it clear, and so state in the guidelines, that any information disseminated prior to October 1, 2002, and thus not subject to the guidelines, will become subject to the guidelines if it is redisseminated after October 1, 2002. We urge the EPA to follow the direction provided by the June 10 OIRA Memo and state that these guidelines will cover information disseminated on or after October 1, 2002, regardless of when the information was first disseminated.

The Draft Guidelines appear to disclaim legal obligations under the Data Quality Act.

The EPA asserts that the applicability of the guidelines can be determined on a case-by-case basis and that the guidelines do not impose any legally binding requirements on the agency. Furthermore, under the information-correction procedures, the EPA states that the "EPA may elect not to correct some completed information products on a case-by-case basis due to agency priorities, time constraints, or resources." The NAM objects to this position. The EPA is bound by the guidelines and states, in part, "The [Data Quality Act] speaks of OMB issuing guidelines under sections 3504(d)(1) and 3516 of the Paperwork Reduction Act. These sections and section 3506(a) of the PRA, in turn provide that each agency shall be responsible for complying with the guidelines prescribed by OMB." The EPA cannot simply disclaim legal obligations under the Data Quality Act.

Conclusion

The NAM appreciates the EPA's efforts to ensure and maximize the quality, objectivity, utility and integrity of information disseminated by the agency and applauds the inclusion of the public in commenting on the Draft Guidelines. The NAM also welcomes the EPA's acknowledgement that the guidelines are a "living document" and may be revised as we all learn how best to address, ensure and maximize information quality. While these NAM comments address six key issues of primary importance to the manufacturing community, we hope that the EPA will review and act upon recommendations submitted by other business trade associations and individual companies. Questions should be addressed to Jeffrey Marks on the NAM staff at (202) 637-3176 or jmarks@nam.org. Thank you.